CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA
PETROLEUM DISTILLATES, REFINED

Chemical Code # 002106, Tolerance # 50792; SB 950 # 788
Original date: November 2, 1987
Revised date: 9/22/88; 7/19/01

I. DATA GAP STATUS

Chronic, rat:	Data gap, no study on file
Chronic, dog:	Data gap, no study on file
Oncogenicity, rat:	Data gap, no study on file
Oncogenicity, mouse:	Data gap, inadequate study, possible adverse effect indicated
Reproduction, rat:	Data gap, no study on file
Teratology, rat:	Data gap, no study on file
Teratology, rabbit:	Data gap, no study on file
Gene mutation:	No data gap, possible adverse effect
Chromosomal aberration:	Data gap, no study on file.
DNA damage:	Data gap, no study on file
Neurotoxicity:	Not required at this time

Toxicology one-liners are attached.
** indicates an acceptable study.
Bold face indicates a possible adverse effect.
File name: T010719

Original: J. Gee, 11/2/87
Revised: M. Silva, 9/88; Kishiyama & Silva, 7/19/01

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

COMBINED, RAT

no study on file

CHRONIC TOXICITY, RAT

no study on file

CHRONIC TOXICITY, DOG

no study on file

ONCOGENICITY, RAT

no study on file

ONCOGENICITY, MOUSE

50792 – 009 115416 is a duplicate (less complete) version of 149 – 013 116794.

REPRODUCTION, RAT

no study on file

TERATOLOGY, RAT

no study on file

TERATOLOGY, RABBIT

no study on file

GENE MUTATION

50792 003 067197 "*Salmonella*/Mammalian Microsome Mutagenicity Test (Ames Test) with Four Lube Oil Stocks, " (Chevron Environmental Health Center, 7/24/81). Lube Oil Stocks (coded PE-2-2, Neutral Oil 20) were tested with *Salmonella typhimurium* TA100 with and without metabolic activation at 0 (vehicle = 0.1 ml DMSO)), 0.01, 0.1, 1.0, 5.0 and 10 mg/plate (triplicate plates). No mutagenic effects were observed at any dose level with TA100 (with or without metabolic activation). Positive controls functioned as expected. NOT ACCEPTABLE (only one tester strain used. Not upgradeable. M. Silva, 9/19/88.

Distillate

** **50792 003 067198** "Ames Test: Pre-incubation Assay of Light Mineral Oil, " (Gulf Life Sciences Center, 3/26/84). Light neutral oil (composition unspecified), was used on *Salmonella typhimurium* tester strains TA97, TA98, TA100, TA1537 and TA 1535 at 0 (vehicle = Pluronic F127--50% w/w in ethanol), 5.0, 10.0, 20.0 and 40.0 mg/plate with and without S-9 activation (triplicate plates). **Possible adverse effect** (an increase in

mutagenicity was observed with TA98 +S-9 at _> 20 mg/plate). No mutagenic effects were observed with other strains with or without activation at any dose level. Positive controls functioned as expected. ACCEPTABLE. M. Silva, 9/20/88.

Distillate

** 50792 - 003 067199 "The Potential of Lube Oil Stocks to Mutate Histidine-deficient strains of *Salmonella typhimurium*," (Chevron Environmental Health Center, Inc., 12/5/80). DG 2486 Neutral Oil 20 (100) was used on *Salmonella typhimurium* strains TA98, TA100, TA1535 & TA1537 at 0 (vehicle = DMSO), 0.1, 1.0 and 10.0 mg/plate with and without activation (duplicate plates). No increase in mutagenicity was observed at any dose with any of the tester strains. The positive controls functioned as expected. ACCEPTABLE. M. Silva, 9/20/88.

50792 – 007 113392 "Determination of Mutagenic Activity of 62-840 towards *Salmonella typhimurium* TA98 Using Modified Ames Assay," (Chopra, C.; Bio-Mutatech, Inc., Woodbridge, Ontario, Canada; Project #: 00096; 9/18/86). *Salmonella typhimurium* strain TA98 was used in a mutagenicity assay with 62-840 (petroleum oil) at 0, 10, 20, 30, 40, 60, 80 and 100% (v/v) both with and without metabolic activation (hamster liver S9) for 48 hours (37°C). Strain TA98 was reported to be sensitive to UV light. There were no treatment-related gene mutation effects at any dose. It was not possible to adequately evaluate the mutagenic potential of 62-840, since there were no toxicity studies and only 1 *S. typhimurium* strain was used. Not acceptable and not upgradeable. There were insufficient data to determine the possibility of an adverse effect. M. Silva, 12/13/01

SUMMARY: Although study 067198 showed a weak mutagenic response with TA98, it is doubtful that petroleum distillates are point mutagens, based on the overwhelming negative response in the other two tests. In fact, the test material was taken to 40 mg/plate and only a weak mutagenic response was observed (twice background). Therefore, petroleum distillates, refined should not be considered to be a point or time-shift mutagen in the Ames test.

CHROMOSOME EFFECTS

no study on file

DNA DAMAGE

no study on file

NEUROTOXICITY

Not required at this time.

MISCELLANEOUS STUDIES

50792 – 004 088471 "Chronic Inhalation Toxicity of a Complex Mineral Oil Mist Atmosphere and Pathology of Repeated Oil Mist Inhalation," (Kwon, B.K., Waritz, R.S., Stula, E.F.; Hazleton Laboratories, TRW Life Science Center, Falls Church, VA; 5/9/90). Mineral oil (#50 + finish adjuvants, such as bacteriostats, surfactants and minor proprietary ingredients) at 0, 5.5 mg/m^3 + 1001 ppm acetone and 105.8 mg/m^3 + 972 ppm acetone was administered by inhalation (5 days/week) to ChRCD rats (both sexes, 1 & 2 years), male Beagle dogs (2 years), ChRCD & CAF/JAX male mice (1 year) and gerbil (both sexes,1 year). There was an increased alkaline

phosphatase activity in lungs of male rats after 2 years of exposure. Relative lung weights (lung/bw) in both sexes of rat at 1 year and in males rats at 2 years (60% increase at 105.8 mg/m^3). Histopathology in rat lungs at 1 and 2 years occurred at 105.8 mg/m^3 (lung oil granulomas, alveolar epithelial metaplasia to cuboidal cells). Dogs after 1 year developed lung oil granulomas. Lesions in the dogs and rats were less than 5% of the lung mass. Rats that were given a 10-month recovery period contained a slightly reduced amount of oil mist lesions. Gerbils and mice at 100 mg/m3 for up to 1 year did not develop lung oil granulomas. Possible adverse effect indicated: Rats and dogs developed lung oil lesions (granulomas) at 100 mg/m^3. These data are supplemental. (Kishiyama and Silva, 12/11/01)